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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,089	12/30/2005	Masayuki Sudoh	016912-0214	8137

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT	PAPER NUMBER
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1626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,089	Applicant(s) SUDOH ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/21 & 10/26/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 are pending in the instant application, of which Claims 2 & 6 are currently amended.

Priority

This application is a 371 of PCT/JP04/09803, filed on 07/09/2004.

Acknowledgement is made of Applicants' claim for priority of Japan 2003-272420, filed on 07/09/2003. Said claim has been made in the ADS and/or in the first paragraph of the Specification.

Information Disclosure Statement

Applicants' information disclosure statements (IDS), filed on 03/21/2006 and 10/26/2006 have been considered. Please refer to Applicants' copies of the 1449 submitted herein.

Response to Restriction

Applicants' election without traverse of **Group I: Claims 1, 3-5 & 7-11** is acknowledged. Further, Examiner acknowledges Applicants' request for reconsideration of the restriction requirement in view of the amended claims: **Group II: Claims 2 & 6**.

Claims 2 & 6 now amended such that both contain 'intended use' language in claims, i.e. "for the production of a compound of formula (I) as defined in Claim 1," however, this language is not further limiting and the invention drawn to **Group II:**

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Claims 2 & 6, is still directed to the subject matter lacking unity of invention with Group

I. Claim 2 is drawn to a method of making an intermediate product, and Claim 6 is drawn to a compound used in the same purpose. The compound in Claim 6 and the method in Claim 2 are drawn to divergent subject matter from Group I. For these reasons, Group II is withdrawn from further consideration as being drawn to a separate invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandala et al. (see Previous Office Action: Mandala *et al.* *Methods of Enzymology* 2000, 311, 335-348). Mandala *et al.* teaches the compound RN 147023-34-5 which anticipates **Claim 3**; however, **Claims 4 & 5** are excluded due to their negative limitations.

Claims 3, 4 & 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Meinz *et al.* (JP 07173123, 07/11/1995; see IDS). Shown in the patent is the compound RN 147023-35-6, wherein **G** = CH₂-Ph on page 2 of the patent.

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Claims 1 & 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Esumi *et al.* (*Tet. Lett.* **1998**, 39, 877-880; see IDS). Shown in **Scheme 2** on page 879 is the conversion of compound **18** to **2**. Compound **18** anticipates **Claim 7** and the reaction transpires in the presence of a coupling agent and a base, anticipating **Claim 1**.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for the *treatment* of Hepatitis C, does not reasonably provide enablement for preventing or treating any or all viral infectious diseases, as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'."

In re Wands, 8 USPQ2d 1400 (1988), discusses the following factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph:

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1. *The nature of the invention;*
2. *The state of the prior art;*
3. *The predictability or lack thereof in the art;*
4. *The amount of direction or guidance present;*
5. *The presence or absence of working examples;*
6. *The breadth of the claims;*
7. *The quantity of experimentation needed; and*
8. *The level of skill in the art*

each of which is discussed in turn below.

The nature of the invention

The nature of the invention is the compounds and compositions of Formula I, the process for preparing these compounds, and methods of using these compounds.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art, namely pharmacological art, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

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In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that a group of compounds and compositions may provide a treatment for Hepatitis C, but it does not mean that the same group of compounds and compositions may prevent Hepatitis C; or treat and/or prevent any and all viral infectious diseases. Furthermore, although progress has been in the development of a Hepatitis C vaccine, to date it does not exist, and therefore could not exist at the time of filing.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance provided which supports Applicant's claimed method for *preventing* or treating any and all viral infectious diseases, as indicated. The direction or guidance present in Applicants' Specification for a method of using the compounds and compositions of Formula I to *treat* HCV activity and HCV growth is found on pages 117-121. Additional information is found in the background on pp. 1-3.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Claims 9-11 are drawn to "preventing and treating a viral infectious disease." In order to prevent a disease, one would need to precisely identify those subjects likely to acquire such a disease, administer Applicant's claimed invention, and then demonstrate that if the identified subject did not develop the disease, such an effect was the direct result of administration of the claimed invention. Furthermore, the scope of the term "viral infectious disease" includes more than just the Hepatitis C virus.

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Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success. **An amendment**, which limits the method of use claims to treating Hepatitis C, would overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

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patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-5 & 8-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **Claims 1-24** of copending Application No. **10/544,896**, filed 8/8/2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter. Although **Claims 4 & 5** of the instant application exclude, in variable **J**, a phenyl group with an -OW group at the para-position, the meta- and ortho-positions are not excluded. The compounds according to formula (I) of the instant application, wherein **A-B-D** are an alkyl chain; **R₁, R₂, R₃** = OH or amino; and **G** = (CH₂)_p-**J**; **J** = substituted aryl overlap significantly with the compositions according to formula (I) of the '896 application such that an infringement on one patent would be an infringement on the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Objections

Claim 10 is objected to because of the following informalities: the claim contains the abbreviation HCV. The claim should contain the full term. Appropriate correction is required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.
Examiner
Art Unit 1626



REBECCA ANDERSON
PATENT EXAMINER

for Joseph K. M^cKane
Supervisory Patent Examiner
Art Unit 1626
Date: May 11, 2007